cont C6

24. The method of claim 22 wherein said growth factor-containing composition comprises vitamin A.

## REMARKS

**Claim Status**

Claims 1, 4, 5, 7-9, 17, 20, 22-24 are in this application.

Claims 2, 3, 6, 10-16, 18, 19 and 21 have been cancelled without prejudice.

Claims1, 4, 5, 7-9, 17 and 20 have been amended.

Claims 22-24 have been added.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

For the Examiner's convenience, a clean copy of the currently pending claims is attached hereto.

**Objection to Claims 1, 3-9, 17 and 20**

The Examiner objects to claims 1, 3-9, 17 and 20 as they encompass non-elected subject matter.

Following the Examiner's suggestion, claims 2, 10-16, 18, 19, 21 have been cancelled without prejudice.

Accordingly, Applicants respectfully request this objection be withdrawn.

**Response to Rejection Under 35 U.S.C. § 112, 2d paragraph**

Claim 6 stands rejected under 35 U.S.C. § 112, second paragraph, as being substantially identical with claim 1.

Because "[c]laim 1 is drawn to treating a tissue that is "transplanted," hence in-vivo and already transplanted," the Examiner considers claim 6 "excessive."

Claim 6 has been cancelled without prejudice. New claim 22 is drawn to treating metanephric tissue with growth factor at the time of or after transplantation.

Accordingly, the rejection of claim 6 under 35 U.S.C. § 112, second paragraph should be withdrawn.

Claim 9 is rejected under 35 U.S.C. § 112, 2d paragraph, as being indefinite regarding the use of "such that." Claim 9 has been amended. "Such that" has a definite meaning, and points to the desired consequence, i.e. "growth factors for metanephric development are present in said recipient's blood that circulates through said metanephric tissue," obtained by a certain way of administering growth factor-containing composition to the recipient.

Therefore, claim 9 in the amended form is allowable under 35 U.S.C. § 112, second paragraph.

**Response to Rejection Under 35 U.S.C. § 102(a)**

Claims 1, 6, 8, 9, and 17 stand rejected under 35 U.S.C. § 102(a) "as being anticipated by EP 0 853 [9]42, published 7/22/98."

As the Examiner is aware, "one's own work is not prior art under § 102(a) even though it has been disclosed to the public in a manner or form which otherwise would fall under § 102(a)." *In re Katz*, 215 USPQ 14 (CCPA 1982) at p. 17. Furthermore, "[a] coinventor need not make a contribution to every claim of a patent." MPEP § 2137.01.

EP 0 853 942 teaches the use of embryonic metanephric tissue from a donor in a method of increasing the functioning nephron mass of a recipient by implanting the metanephric tissue next to the recipient's omentum or under the renal capsule of the recipient's kidney. EP 0 853 942 further discloses growth factor (including VEGF) treatment of metanephric tissue at the time of and/or after transplantation, but is silent with respect to growth factor treatment of metanephric tissue before transplantation. A declaration by Dr. Hammerman is submitted, which states that he is the sole inventor of the invention relating to the use of growth factors (including VEGF) to treat metanephric tissue at the time of and/or after transplantation.

As also indicated in his declaration, the subject matter described in EP 0 853 942 is his own invention. Because it was not published more than a year before the effective filing date, EP 0 853 942 cannot be used as prior art under § 102(a) against amended claim 22 and its dependent claims 8-9, and 23-24. Moreover, given the amendment to claim 1 and its dependent claims, the claims are also novel over EP 0 853 942.

**Response to Rejection Under 35 U.S.C. § 103(a)**

Claims 1, 3-9, 17 and 20 are rejected under 35 U.S.C. § 103(a) "as being obvious over EP 0 853 [9]42."

Applicants already pointed out that EP 0 853 942 is not available as prior art against amended claim 22 and its dependent claims 8-9, and 23-24, because the invention claimed is solely that of Dr. Hammerman who is the sole author of EP 0 853 942. EP 0 853 942 is therefore not prior art under 35 U.S.C. § 103(a) against these claims.

With regard to claims 1, 4, 5, 7, 17 and 20, Applicants note that there are three requirements to establish a prima facie case of obviousness. These include that "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." (MPEP § 2143).

EP 0 853 942 is discussed above. Although EP 0 853 942 discloses Dr. Hammerman's sole invention of growth factor treatment of metanephric tissue at the time of or after transplantation, EP 0 853 942 is silent with respect to growth factor treatment of metanephric tissue before transplantation. In fact, EP 0 853 942 teaches away from contacting metanephric tissue for transplantation *in vitro* prior to the transplanting operation. On p. 4, line 31-32, the reference explicitly points out, "[metanephroi] should be transplanted as soon as possible into the recipient, preferably within one hour after removal from the embryonic donor, and more preferably within 30 minutes."

In contrast, claim 1 and its dependent claims 4, 5, 17 and 20 are directed to a method of contacting metanephric tissue for transplantation *in vitro* prior to the transplanting operation.

Furthermore, as disclosed in the specification of this application (p.8, line 2-6), pretreatment of metanephric tissue with a growth factor composition "exerts a positive effect in a surprisingly short period of time," and "[s]ignificant improvement in the development of the implant can be achieved when the metanephric tissue is contacted with the growth factor composition *in vitro* for less than 24 hours." As stated by Dr. Hammerman in his declaration, this was an unexpected result.

Therefore, EP 0 853 942 does not teach or suggest the subject matter in claim 1 and its dependent claims 4, 5, 17 and 20. Moreover, prior to conducting the actual experiment, there was no reasonable expectation that growth factor pretreatment of metanephric tissue would be beneficial, because the reference explicitly emphasizes minimizing the time lag between removal of metanephric tissue from a donor and transplantation into a recipient.

EP 0 853 942 also does not teach or suggest treating the implanted metanephric tissue at the time of ureteroureterostomy. The reference teaches that "growth factors are preferably administered to the host continuously, for example, by subcutaneous osmotic pumps, until the metanephric tissue

has sufficiently developed," or "to the site of implant at the time of implantation," *see* page 5, lines 12-15. Furthermore, as shown in Example 6 of the specification in this application (page 18, lines 24-30), the transplanted metanephroi bathed in VEGF-containing medium for 45 minutes at the time of ureteroureterostomy functions significantly better than the non-treated transplant. As stated by Dr. Hammerman in his declaration, this was an unexpected result. Thus, the subject matter in claim 7 and its dependent claims are patentable over EP 0 853 942.

Therefore, a prima facie case of obviousness has not made with respect to claims 1, 4, 5, 7, 17 and 20. Accordingly, Applicants respectfully submit that claims 1, 4, 5, 7-9, 17, 20, 22-24 are allowable under 35 U.S.C. § 103(a).

Applicants submit the claims are now in condition for allowance and an early notification of such is respectfully solicited. If after review, the Examiner feels there are further unresolved issues, the Examiner is invited to call the undersigned at (415) 781-1989.

Respectfully submitted,

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Dated: Oct 1, 2001

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## VERSION WITH MARKINGS TO SHOW CHANGES MADE



1. (Amended) A method for the treatment of metanephric tissue for transplantation [that is transplanted] into a recipient comprising contacting said metanephric tissue, *in vitro*, with a growth factor-containing composition comprising one or more growth factors for metanephric development prior to transplanting said metanephric tissue into said recipient.

4. (Amended) The method of claim 1 [3] wherein said metanephric tissue is contacted with said growth factor-containing composition for less than 8 hours.

5. (Amended) The method of claim 1 [3] wherein said metanephric tissue is contacted with said growth factor-containing composition for less than 2 hours.

7. (Amended) A method for the treatment of metanephric tissue transplanted into a recipient comprising contacting said transplanted metanephric tissue with a growth factor-containing composition comprising one or more growth factors for metanephric development, [The method of claim 6] wherein said growth factor-containing composition is administered to said transplanted metanephric tissue at the time a ureteroureterostomy is performed.

8. (Amended) The method of claim 22 [6] wherein said growth factor-containing composition is administered to said metanephric tissue by an osmotic pump.

9. (Amended) The method of claim 22 [6] wherein said growth factor-containing composition is administered to said recipient in a manner such that said one or more growth factors for metanephric development are present in said recipient's blood that circulates through said metanephric tissue.

17. (Amended) The method of claim 1 or 7 wherein said growth factor-containing composition comprises vascular endothelial growth factor.

20. (Amended) The method of claim 1 or 7 wherein said growth factor-containing composition comprises vitamin A.

New Claims:

22. (New) A method for the treatment of metanephric tissue comprising contacting said metanephric tissue, *in vivo*, with a growth factor-containing composition comprising one or more growth factors for metanephric development at the time of or after being transplanted into said recipient.

23. (New) The method of claim 22 wherein said growth factor-containing composition comprises vascular endothelial growth factor.

24. (New) The method of claim 22 wherein said growth factor-containing composition comprises vitamin A.